

SETTLEMENT AGREEMENT

This Settlement Agreement is entered into this 17<sup>th</sup> day of May 1999, by and between the United States of America, including the Department of Health and Human Services, Health Care Financing Administration ("HCFA") and the Office of Inspector General ("OIG") (collectively "United States"), and Integrated Health Services at Penn, Inc., d/b/a ~~Integrated Health~~ Services of Bryn Mawr at the Chateau ("IHS"), to resolve the pending and potential civil and administrative claims more fully described herein.

WHEREAS, IHS is a for-profit corporation engaged in the provision of healthcare services to residents of long-term care facilities;

WHEREAS, IHS leases and operates a skilled nursing facility, IHS of Bryn Mawr at the Chateau, located at 956 Railroad Avenue, Bryn Mawr, PA., 19010 ("the Chateau");

WHEREAS, as a result of an investigation by the United States Attorney's Office and the Department of Health and Human Services, the United States of America contends that at certain times during 1996 IHS provided inadequate care to some residents at the Chateau by failing to provide adequate nutrition in a timely manner in view of the current clinical condition of those residents and adequate incontinence care;

WHEREAS, Civil Monetary Penalties were imposed by HCFA on two separate occasions within calendar year 1996;

WHEREAS, IHS denies any wrongdoing, inadequacy or liability in regard to the care rendered to residents of the Chateau and has appealed the imposition of Civil Monetary Penalties by HCFA;

WHEREAS, the parties wish to resolve this matter in an amicable manner without the need for protracted litigation;

WHEREAS, the parties agree that this Agreement does not constitute and shall not be construed as an admission of any liability, inadequacy or wrongdoing on the part of IHS;

NOW THEREFORE, for and in consideration of the mutual covenants and conditions contained herein and other good and valuable consideration, the parties intending to be legally bound enter into the following:

1. IHS agrees to pay the sum of One Hundred and Ninety-Five Thousand Dollars (\$195,000.00) to the United States in settlement of its potential civil or administrative liability to the United States as described in paragraphs 15 through 17 for the matters described in paragraphs 15 through 17. The settlement amount shall be paid by IHS within seventy-two (72) hours of receipt by IHS of a copy of this Settlement Agreement fully executed by all of the United States signatories listed at the end of this Agreement. The Settlement Agreement will be effective upon receipt by the United States of the settlement

amount. Payment of the settlement amount shall be to the United States Attorney's Office, 615 Chestnut Street, Suite 1250, Philadelphia, PA 19106, Attn: David R. Hoffman.

2. IHS and its agents, employees, contractors, and/or subcontractors agree to abide by a nutritional monitoring program for residents at the Chateau that, at a minimum, includes implementation of and compliance with the Standards of Practice and Practice Guidelines for "Medical Nutrition Therapy for Pressure Ulcers/Wounds," "Weights-Monitoring of," and "Weight Committee" which are attached hereto as Exhibit A.

3. IHS agrees to ensure that each resident is provided with adequate skin care, nutrition, turning and positioning to decrease the likelihood of skin breakdown. While not bound to all provisions of the Clinical Practice Guidelines for the Prediction, Prevention and Treatment of Pressure Ulcers promulgated by the Agency for Health Care Policy Research ("Guidelines"), IHS agrees to use the Guidelines as a basis to establish IHS's individualized care plan for skin and wound care. In addition, IHS agrees to fully comply with its own protocols and procedures for skin and wound care set forth in its skin and wound care manuals.

4. IHS agrees to provide training in which all dietary management and nursing staff at the Chateau will participate on all of the requirements set forth in the documents referred to in this Settlement Agreement within forty-five (45)

days of the execution of this Agreement. Thereafter, this training shall be provided on at least an annual basis, and all new dietary management and nursing staff at the Chateau shall be trained on the requirements set forth in the documents contained herein within twenty (20) days of such employee's commencing employment with the Chateau.

5. IHS agrees that it will provide enteral and parenteral feedings only for those residents at the Chateau who are unable to obtain adequate nutritional intake orally and whose clinical condition demonstrates that enteral/parenteral feedings are unavoidable, while at the same time honoring physician orders and the residents' Advance Directive choices, if available.

6. IHS agrees that it will provide residents at the Chateau with appropriate incontinence care in accordance with all applicable laws and regulations in a timely fashion.

7. IHS agrees that the Chateau will comply fully with the applicable laws, rules and regulations governing the Medicare and Medicaid Program and the Nursing Home Reform Act.

8. IHS agrees to hire an independent third party, Cathy Hess (the "Consultant"), to assist the Chateau in providing quality care and in complying with the terms of this Settlement Agreement. The Consultant shall visit the Chateau for a period of one (1) year from the date of execution of this Agreement and shall have access to all current nursing home residents and their medical records. During the one (1) year period, the Consultant

shall visit the Chateau at least monthly for the first three (3) months and thereafter as needed, but in any event the Consultant shall not spend more than 90 hours in the facility during the one (1) year period, unless unforeseen or emergency circumstances occur or unless otherwise agreed to by the parties to this Agreement. Time spent by the Consultant under this Agreement travelling to or from the facility or writing reports shall not count against the 90 hours. At the conclusion of each visit, the Consultant will meet with the Chateau Administrator (or his/her designee) to make suggestions related to care in the facility or concerning compliance with the provisions of this Agreement. The Consultant shall share these suggestions with the United States. The Consultant's visits shall be focused primarily on improving wound care, nutrition and incontinence care at the Chateau, but the Consultant shall be free to assess and comment on other issues relating to quality of care which come to the Consultant's attention during such visits. Within ten (10) calendar days of each visit, the Consultant will provide IHS, the U.S. Attorney's Office, HHS-OIG, HCFA and the local Long-Term Care Ombudsman Program with a written report describing the results of the visit. Upon receipt of the report, IHS will have an opportunity to submit a response, with the assistance of the Consultant as requested, to address any concerns raised by the Consultant and actions taken by IHS in response to such concerns. Such response, if any, shall be submitted within ten (10) business

days of receipt by IHS of the Consultant's report. IHS and the United States agree that, at the request of either party, they shall meet promptly to discuss any issues or concerns raised by the Consultant. IHS and the United States agree that IHS is not required by this Agreement to follow any recommendations or suggestions made by the Consultant, and the failure or refusal of IHS to follow any such recommendation or suggestion by itself is not per se a breach of this Agreement nor per se proof of such a breach. In the event the United States believes there has been a breach of this Agreement, nothing in this Agreement shall prevent the United States from calling the Consultant as a witness in any proceeding. At all times the Consultant shall attempt to coordinate his or her activities with relevant IHS personnel in order to minimize disruption in the day-to-day operations of the facility. In order to minimize any disruption to the day-to-day operations, the Consultant shall give IHS and the United States at least 48 hours advance notice of his/her visits to the Chateau. In the event the Consultant's visit is for two or more consecutive days, 48 hours advance notice shall only be required for the first day of the visit. In the event that the Consultant reasonably concludes that less notice is warranted in order to fulfill her responsibilities under this Agreement, the Consultant may provide less than 48 hours notice of her visit.

9. In the event that the Consultant's report identifies a situation which the United States believes

immediately jeopardizes the health and safety of residents of the Chateau, the United States may take whatever action authorized by law it deems necessary to ensure the health and safety of the residents.

10. In the event that IHS fails to comply in good faith with any of the terms of this Agreement relating to the Chateau, or should any of IHS's representations or warrants be materially false, the United States may, at its sole discretion, exercise one or more of the following rights:

(a) seek specific performance of this Agreement and the prevailing party shall be entitled to an award of reasonable attorneys fees and costs in its favor; or

(b) exercise any other right granted by law.

11. In the event that the United States exercises any of its rights under paragraphs 9 or 10 of this Agreement, IHS specifically reserves all of its rights to challenge, defend and contest any such action.

12. Each party to this Agreement shall bear its own costs except as otherwise provided herein.

13. IHS and its agents, employees, contractors and/or subcontractors agree that they have not and will not take any retaliatory action against any individual or individuals who cooperated with this investigation.

14. Except as specifically provided in paragraph 8 of this Agreement with respect to the Consultant, the obligations

imposed by this Agreement on IHS in paragraphs 2, 3 and 4 shall be in effect for a period of three (3) years from the date of execution of this Agreement. During that three-year period, on or before the first, second and third anniversary date of this Agreement, IHS will certify to HHS-OIG that, to the best of its knowledge and belief, it has complied with the requirements of paragraphs 2, 3 and 4.

15. In consideration of the promises made by IHS in this Settlement Agreement and conditioned upon payment in full of the settlement amount referenced in paragraph 1, the United States, on behalf of itself, its officers, agents, agencies, and departments, hereby releases and discharges IHS, its parents, affiliates, agents, employees, contractors, and subcontractors from any and all civil or administrative monetary claims (including recoupment claims), actions, causes of action, liabilities, losses, and damages, including attorneys' fees, costs and expenses, which the United States has asserted or could have asserted against IHS, its parents, affiliates, agents, employees, contractors, and subcontractors under the False Claims Act, 31 U.S.C. §§ 3729, et seq., the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812, and common law for (1) any deficiencies cited or found in any surveys or inspections conducted by the Pennsylvania Department of Health at the Chateau from January 1, 1996 to the date of execution of this Agreement and (2) the



adequacy of care provided during the period January 1, 1995 to January 1, 1997, to the eight nursing home residents listed in Attachment A to the HHS-OIG subpoena dated April 18, 1996 addressed to the Custodian of Records of the Chateau.

16. In consideration of the obligations of IHS as set forth in this Agreement, and conditioned upon payment in full of the settlement amount referenced in paragraph 1, HHS-OIG agrees to release and refrain from instituting, directing or maintaining any administrative claim or any action seeking exclusion from the Medicare, Medicaid or other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against IHS, its parents, affiliates, agents, employees, contractors, and subcontractors, under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law), 31 U.S.C. §§ 3801-3812 (Program Fraud Civil Remedies Act) or 42 U.S.C. § 1320a-7(b) (permissive exclusion), for the conduct set forth in the preceding paragraph, except as specifically reserved in Paragraph 17.

17. The parties agree that the releases given in the preceding two paragraphs specifically exclude the following:

a. Any civil or administrative disputes, adjustments or claims relating to matters other than those for (1) any deficiencies cited or found in any surveys or inspections conducted by the Pennsylvania Department of Health at the Chateau from January 1, 1996 to the date of execution of this Agreement and (2) the adequacy of care provided during the period January

1, 1995 to January 1, 1997, to the eight nursing home residents listed in Attachment A to the HHS-OIG subpoena dated April 18, 1996 addressed to the Custodian of Records of the Chateau.

b. Any civil, criminal or administrative disputes or claims arising under the Internal Revenue Code, Title 26 of the United States Code.

c. Any disputes or claims arising under any express or implied warranties relating to products or services other than those released in paragraphs 15 and 16.

d. Any disputes or claims arising under the criminal laws of the United States and any related administrative action for mandatory exclusion pursuant to 42 U.S.C. § 1320a-7(a).

e. Subject to the enforcement provisions of paragraphs 9 and 10, any obligations created by this Agreement.

f. Any HHS-OIG administrative exclusion action pursuant to 42 U.S.C. § 1320a-7a or 42 U.S.C. § 1320a-7(b), or any civil money penalty or termination action by HCFA, if any such action is based on events occurring after the date of execution of this Settlement Agreement.

18. IHS agrees that all costs (as defined in the Federal Acquisition Regulation ("FAR") § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. § 1395 et seq., and §§ 1396 et seq., and the regulations promulgated thereunder) incurred by or on behalf of defendants, in connection

with: (a) the government's investigations, and IHS's investigation and defense of this matter, (b) the negotiation of this Agreement, (c) any corrective action undertaken by IHS for the released acts during the relevant period, and (d) the payments made to the United States pursuant to this Settlement Agreement, shall be unallowable costs for government contract accounting and for Medicare, Medicaid, CHAMPUS, VA and FEHBP reimbursement purposes. These amounts shall be separately estimated and accounted for by IHS, and IHS will not charge such costs directly or indirectly to any contracts with the United States or any State Medicaid program, or to any cost report, cost statement, or information statement submitted by IHS, to CHAMPUS, VA or FEHBP programs. IHS agrees further that within 60 days it will identify to applicable Medicare and CHAMPUS fiscal intermediaries, carriers and/or contractors, and Medicaid fiscal agents any unallowable costs (as defined in this paragraph) included in payments sought in any cost reports, cost statements or information reports already submitted by IHS or any of its subsidiaries and will request that such cost reports, cost statements or information reports, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Any payments due after the adjustments have been made shall be paid to the United States at the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any

calculations submitted by IHS or any of its subsidiaries on the effect of inclusion of unallowable costs (as defined in this paragraph) on IHS's, or any of its subsidiaries' cost reports, costs statements or information reports. Nothing in this Agreement shall constitute a waiver of the rights of HHS, or any Medicare or CHAMPUS fiscal intermediary or contractor, or any Medicaid fiscal agent, to examine or re-examine the unallowable costs described in this paragraph.

19. In consideration for such repose and on the terms and conditions contained herein, IHS fully and finally releases, dismisses, and forever discharges the United States, its agencies, employees, servants, and agents, from any and all claims, causes of action, liabilities, losses, appeals of remedies imposed by HCFA or HHS-OIG, and damages, including attorneys' fees, costs and expenses which IHS has asserted or could have asserted against the United States, its agencies, employees, servants, and agents, for (1) any deficiencies cited or found in any surveys or inspections conducted by the Pennsylvania Department of Health at the Chateau from January 1, 1996 to the present and (2) the adequacy of care provided during the period January 1, 1995 to January 1, 1997, to the eight nursing home residents listed in Attachment A to the HHS-OIG subpoena dated April 18, 1996 addressed to the Custodian of Records of the Chateau. IHS agrees that within five (5) days of the execution of this Agreement, it will notify the

Administrative Law Judges presiding over all administrative appeals filed by IHS pertaining to remedies imposed by HCFA for IHS of Bryn Mawr at the Chateau, that the appeals are withdrawn with prejudice and that all requests for hearings are also withdrawn with prejudice.

20. This Agreement constitutes the complete agreement between the parties and may not be amended except by the written consent of the parties.

21. The undersigned individuals signing this Agreement on behalf of IHS represent and warrant that they are authorized by IHS to execute this Agreement. The undersigned United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.


22. Each party to this Agreement will bear its own legal and other costs incurred in connection with this matter.

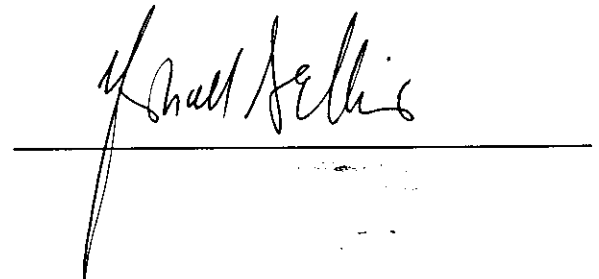
23. This Agreement shall be binding on the heirs, administrators, executors, successors, and transferees of IHS.

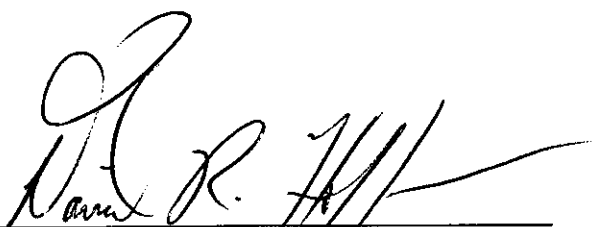
UNITED STATES OF AMERICA:


INTEGRATED HEALTH SERVICES AT  
PENN, INC.:


MICHAEL R. STILES  
UNITED STATES ATTORNEY

  
JAMES G. SHEEHAN  
ASSISTANT U.S. ATTORNEY  
CHIEF, CIVIL DIVISION



  
\_\_\_\_\_  
DAVID R. HOFFMAN  
ASSISTANT U.S. ATTORNEY

  
\_\_\_\_\_  
LEWIS MORRIS  
ASSISTANT INSPECTOR GENERAL  
OFFICE OF COUNSEL TO THE INSPECTOR GENERAL  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

  
\_\_\_\_\_  
JAN M. LUNDELIUS  
ASSISTANT REGIONAL COUNSEL  
REGION III  
HEALTH CARE FINANCING ADMINISTRATION

## EXHIBIT A

**SUBJECT:**            **MEDICAL NUTRITION THERAPY FOR PRESSURE ULCERS/  
WOUNDS**

**STANDARD:**

Patients/Residents with pressure ulcers/wounds receive nutrition therapy to promote healing.

**PRACTICE GUIDELINE:**

1. The Registered Dietitian is notified by the nursing department via the weekly skin report when a patient/resident develops a pressure ulcer/wound. When a patient/resident is admitted with a pressure ulcer/wound, the Registered Dietitian is notified by the nursing staff.
2. The Registered Dietitian evaluates and documents the patient's/resident's nutritional status at the time he/she is notified of a pressure ulcer/wound and at least weekly until it is healed.
3. Based on the Registered Dietitian's assessment, the nutrient needs of the patient/resident with a pressure ulcer/wound may be increased as follows:
  - a.     Protein:            Stage I and II            1.0 - 1.5 Gm/Kg  
                              Stage III and IV        1.5 - 2.0 Gm/Kg  
                              Multiple pressure ulcers/wounds: 1.5 - 2.0 Gm/Kg  
                              -More protein may be indicated for wounds that are not healing;  
                              monitor lab data and fluid intake.
  - b.     Fluid:              35 - 40 cc/Kg/day

A multivitamin, vitamin C or zinc sulfate *may* be indicated, although long term zinc supplementation should be avoided to prevent copper deficiency and other metabolic derangements.
4. The following nutritional interventions for patients/residents with pressure ulcers/wounds are suggested, but not meant to be all inclusive or required, and may be initiated by the Registered Dietitian as deemed appropriate (unless contra-indicated by diagnosis, medical condition or diet order):
  - a.     One extra serving of meat, protein or egg at breakfast.
  - b.     One extra ounce of meat or protein at lunch and/or dinner.
  - c.     4 oz. of Vitamin C Juice at each meal.
  - d.     8 oz. of milk at each meal.
  - e.     Fortified supplement or shake two or three times/day between meals.
  - f.     2,000 + cc of fluid/day encouraged by both nursing and dietary.



**SUBJECT: MEDICAL NUTRITION THERAPY FOR PRESSURE ULCERS/  
WOUNDS (CONTINUED)**

5. The medical nutrition therapy for these patients/residents is individualized and assessed for acceptance by the patient/resident to ensure effectiveness. If there is an inadequate dietary intake of protein or calories, care givers should first attempt to discover the factors compromising intake and offer support with eating. Other nutritional supplements or support may be needed. If dietary intake remains inadequate and if consistent with overall goals of therapy, more aggressive nutritional intervention such as enteral or parenteral feedings should be considered.  
(AHCPR Pressure Ulcers in Adults: Prediction and Prevention, Clinical Practice Guideline Number 3, 7. Nutritional Deficit)
6. Pressure ulcer/wound information is communicated to all team members during wound rounds and/or at each interdisciplinary team meeting.
7. The Registered Dietitian evaluates the need for continued medical nutrition therapy when the pressure ulcer/wound is healed.

## **NURSING STANDARDS OF PRACTICE**

### **SUBJECT: WEIGHTS - MONITORING OF**

### **STANDARD:**

1. The Basic Medical patient/resident will be weighed monthly or per physician's order.
2. The Subacute patient/resident will be weighed weekly or per physician's order.
3. All residents identified to be a nutritional risk will be weighed weekly.

### **PRACTICE GUIDELINES:**

1. Record weights, equipment ID code and date obtained on the Weight Worksheet.
2. Charge Nurse will chart weights from Weight Worksheet into residents' Medical Records.
3. If the month to month weight shows more than a three percent gain or loss, the patient/resident is reweighed immediately under the supervision of a nurse.
4. The Charge Nurse will notify Dietitian of weight change > 3% in 30 days, 7.5% in 90 days, or 10% in 180 days using the 3 part Dietary Communication Form. Part 1 is sent to the Dietitian, part 2 is sent to the Clinical Coordinator and part 3 is placed in the Dietary section of the Medical Record.
5. The Charge Nurse will notify the patient/resident/family, physician and Dietitian if there is an actual five percent (5%) or more gain or loss in one month and will document weight change and notification in Nurses' Notes.
6. Charge Nurse will complete Action Plan: Significant Weight Changes form for all residents with a > 3% weight change in 30 days or less. Clinical Coordinator will review these forms weekly and will yellow out entries when completed. Resident names may be re-entered on form if problems recur.
7. The Dietitian reviews the patient's/resident's nutritional status and makes recommendations for intervention in the nutritional progress notes if significant weight change is noted and notifies nursing using the Nutritional Recommendation form. The Dietitian will keep one copy of this form, place a copy in the Dietary Section of the Medical Record, and give another copy to the Clinical Coordinator who will contact physicians for telephone verbal orders as needed. The Clinical Coordinator will document follow-up on the Nutritional Recommendation form and return it to the Dietitian. Once recommendations have been implemented, the Dietitian will yellow out the recommendation.
8. Significant, unplanned changes in weights are reviewed weekly at the Weight Committee Meeting following Weight Committee Standards of Practice.

# NURSING STANDARDS OF PRACTICE

## **SUBJECT: WEIGHT COMMITTEE**

### **STANDARD:**

Patients/Residents with identified significant weight changes, gradual weight variance trends, and residents identified at risk for weight gain/loss will be reviewed at the Weight Committee meeting to help maintain acceptable parameters of nutritional status.

### **PRACTICE GUIDELINE:**

1. The Weight Committee meets weekly to review patients/residents identified to be at nutritional risk due to :
  - \* Weight change > 3% in 30 days
  - \* Weight change > 7.5% in 90 days
  - \* Weight change > 10% in 180 days
  - \* New diagnosis of depression
  - \* Consumes < 75% of 1-2 meals/day for 3 consecutive days
  - \* Tube feeding
  - \* Pressure ulcers
  - \* Abnormal albumin according to below parameters in number 4.
2. The Weight Committee includes the following members: Dietitian, Clinical Coordinator, Director of Rehab Services, RNAC, and DON.
3. Identified patients/residents are reviewed by the Committee to determine the reason for weight variance and plan interventions to prevent further weight change and improve weight status. Information on these patients/residents is noted on the Action Plan: Significant Weight Changes form.
4. Action parameters are as follows:
  - a. Albumin level to be obtained monthly on all residents with pressure ulcers or tube feeding.
  - b. Albumin levels will be done on Admission on all residents with a pressure ulcer score of 8 or above on the Pressure Sore Risk Assessment, a score of 16 or less on the Braden Scale, or a history of weight loss.
  - c. Albumin level will be done on admission and quarterly x 2 if resident has had an Albumin level of < 3.5 within the last 3 months. If no weight loss after 6 mos. Albumin annually.
  - d. Albumins will be completed every 6 mos. on residents who continue to score > 8 on the Pressure Sore Risk assessment or < 16 on the Braden Scale.
  - e. Albumins will be completed quarterly x 2 on any resident with a history of pressure sores, or past history of significant weight loss. If no weight loss or skin breakdown is noted after 6 months, albumin will be checked annually there after.

- f. Prealbumin may be useful to monitor protein stores in patients/residents with pressure ulcers. The Dietitian will request an order for prealbumin when a resident has a stage 3 or 4 pressure ulcer. Prealbumin will be rechecked weekly until the lab results and/or other clinical indicators, such as wound healing, indicate positive nitrogen balance. If the request for prealbumin levels is denied, the physician will be asked to document that the patient/resident is in positive nitrogen balance.
- g. Residents found "at risk" by the Weight Committee who exhibit any of the following will have an albumin level checked:
  - \* Abnormal hemoglobin and hematocrit in the past month
  - \* Variable oral intake in the past month
  - \* Poor dentition
  - \* Weight loss > 3% in the past month
  - \* New psychiatric diagnosis or exacerbation of an existing psychiatric condition.

5. Residents found to be at risk will have the following:

- a. Albumin order
- b. Weekly weights
- c. Care Plan update
- d. Evaluation by Dietitian within 3-4 days of "risk determination" to include:
  - \* Assessment of nutritional/hydration status
  - \* Albumin evaluation
  - \* Update caloric, fluid and protein needs
  - \* Determination of ideal body weight
  - \* Dietitian's progress note to include the above as well as prior weights, pertinent labs and interventions.
- e. Monthly assessment by the Dietitian

6. A new Minimum Data Set is triggered due to significant, unplanned weight change as follows:  
5% in 30 days, 7.5% in 90 days, or 10% in 180 days.

7. The Dietitian will update the Plan of Care to reflect weight changes with appropriate goals and approaches/interventions listed.